

REMARKS

Reconsideration of the present application is respectfully requested in view of the above Amendments and the following remarks. Claims 33-42 were pending. Claim 33 has been amended to point out with particularity and claim distinctly a certain specific embodiment of Applicants' invention. Claims 35-37 and 40-42 have been canceled. Support for amended claim 33 may be found, in part, in previous claim 37 (*see also* specification at page 21, lines 24-30). The Amendment submitted herewith is not to be construed as acquiescence to the stated grounds for rejection and is made without prejudice to prosecution of any subject matter modified or removed by this Amendment in a related divisional, continuation, or continuation-in-part application. No new subject matter has been added. Accordingly, upon entry of these amendments, claims 33, 34, 38, and 39 will be pending.

Rejection Under 35 U.S.C. § 103

The Examiner has rejected claims 33-42 under 35 U.S.C. § 103(a) for allegedly being obvious over Samagadharan et al. (U.S. Patent No. 5,116,740 (1992)), in view of Lowell (U.S. Patent No. 5,726,292 (1998)) and Anselem et al. (U.S. Patent No. 5,116,740 (1998)).

Applicants respectfully traverse this rejection and submit that the present claims meet the requirements for nonobviousness under 35 U.S.C. § 103. Each of the cited documents alone or in any combination fails to teach or suggest a process for inducing a neutralizing antibody response in a subject against HIV wherein the process comprises administering an immunogenic composition directly to mucous membranes, and wherein the immunogenic composition comprises (1) a C-terminal truncated gp160 protein antigen as recited that consists essentially of the amino acid sequence set forth at residues 33-681 of SEQ ID NO:1; (2) proteosomes that are complexed or coupled with the antigen; and (3) bioadhesive nanoemulsions.

None of the cited documents alone or in any combination teaches or suggests an immunogenic composition that comprises a truncated gp160 protein having the recited amino acid sequence and that such a polypeptide may be complexed with proteosomes and combined with bioadhesive nanoemulsions for immunizing subjects against HIV. Each cited document

fails to teach or suggest that portions of gp160 may be removed and that the remaining portion would be useful as an immunogenic composition when combined with proteosomes. More specifically, none of the cited documents alone or in any combination provides any motivation, teaching, or suggestion to make and use a polypeptide consisting essentially of the amino acid sequence set forth at residues 33-681 of SEQ ID NO:1 as a component of an immunogenic composition.

Instead, each of the cited documents describes use of full-length gp160 as an immunogen. Sarnagadharan et al. teach that an object of their invention is to provide “intact HIV gp160 in its native form,” particularly instead of a recombinant polypeptide (*see* column 2, lines 13-14 and column 1, line 63 through column 2, line 2). Moreover, the variation in amino acid sequence of HIV polypeptides, particularly gp160 and its cleavage products, gp120 and gp41, is well understood in the art and varies with HIV isolates (*see, e.g.*, Sarnagadharan et al., column 5, lines 23-26). Accordingly, in the absence of the disclosure in the present application, a person having ordinary skill in the art could not predict the amino acid sequence of the particular truncated gp160 protein antigen that is taught in the present application and would have no desire to make and use this HIV antigen.

Applicants therefore respectfully submit that a *prima facie* case of obviousness has not been established and that the claimed subject matter is nonobvious as required under 35 U.S.C. § 103. Applicants therefore respectfully request that the rejection of the claims be withdrawn.

Applicants submit that claims 33, 34, 38, and 39 in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
SEED Intellectual Property Law Group PLLC

/Mae Joanne Rosok/

Mae Joanne Rosok
Registration No. 48,903

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

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